SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING NOVEMBER 1, 2000

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, November 1, 2000, at 9:00 a.m. and at 1:30 p.m. Pacific Standard Time (PST) as part of the Sixth NELAC Interim Meeting in Las Vegas, NV. The meeting was led by its chair, Mr. Scott Siders of the Illinois Environmental Protection Agency. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss proposed changes to Chapter 5, activities of the asbestos subcommittee, the performance-based measurement system (PBMS) Straw Model, integration of the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025, and changes to D.1 proposed by the Environmental Laboratory Advisory Board (ELAB)*

INTRODUCTION

Mr. Siders opened the meeting by introducing the committee members and reviewing the published agenda. The facilitator, Mr. Mike Beard of Research Triangle Institute (RTI), reviewed the ground rules for the session. Mr. Siders indicated that the priorities for the committee were established at the Sixth NELAC Annual Meeting (NELAC 6). He noted that delays with release of the revised Chapter 5 after NELAC 6 were due to the copyright issue with the American National Standards Institute (ANSI). Mr. Siders reviewed the committee's guiding principles, noting that January 19,2001 is the deadline for comments; he requested that all comments be submitted in writing in the format posted on the NELAC Website. He also noted that March 19, 2001, is the deadline for completing proposed changes to the standards; and April 16, 2001 is the deadline for posting proposed changes to the NELAC Website.

TOPICS OF DISCUSSION

ELAB Proposed Changes to Appendix D.1

Mr. Siders noted that the changes proposed by he Environmental Laboratory Advisory Board (ELAB) have been discussed by the committee in detail. Mr. Jerry Parr of ELAB reviewed the proposed changes, noting that the frequency of matrix spikes should be the client's decision, based on the data quality objectives. Mr. Siders then opened the floor for comments.

Comments on the ELAB-proposed changes favored incorporating them in the committee's proposed changes to be voted on for adoption at the Seventh NELAC Annual Meeting (NELAC 7). The committee could recommend that implementation be immediate, and no later than two years. It was suggested that all acronyms and terms be defined in the glossary and that editorial review of the chapter be done.

Matrix Spike Issues

Questions on the meaningfulness of matrix spike results and the consistency of performance by all laboratories were raised, however, it was agreed that matrix spikes should be performed on the client's matrix, when requested by the client. It was noted that implementation of a spiking procedure involves consideration of compound compatibility, concentration levels, possible surrogates, spiking frequency and sources of authentic standards. It was noted that the purpose is to verify that the measurement process is in control rather than the control of specific compound performance.

Quality Control

The difficulty of establishing control and reporting limits for blanks, negative controls and matrix spikes was discussed, including recently received comments from the Department of Defense. Differentiating between the acceptability and non-acceptability of out-of-limit results, by compound, was noted, as was the statistical aspect of the issue. Also, the limitation of the sole use of control and reporting limits, rather than other measures of system performance (e.g., trend analysis), was noted. There was a question on the appropriateness of NELAC-specified limits, since many limits are specified in a method.

PBMS STRAW MODEL DISCUSSION

Mr. Siders asked the ELAB subcommittee to summarize for the committee the PBMS straw model it had presented during the Opening Plenary session. Key elements are method selection, verification, modification, development, and documentation; and data evaluation and assessment. The straw model works within the existing structure and hierarchy for methods; regulatory changes are anticipated, as are new method validation approaches. At the recommendation of the subcommittee, Mr. Siders will chair a Quality Systems subcommittee to work specifically on the PBMS issue.

In subsequent discussion, the relevance of ISO 17025, EPA's contract laboratory program statement of work, and American Society for Testing and Materials (ASTM) work group on data reporting requirements were noted to the committee. It was pointed out that the purpose of the measurements, how good the measurements need to be, etc. must be answered before the straw model is applied. The issue of acceptability of PBMS by the user community was also raised.

ASBESTOS SUBCOMMITTEE

Dr. George Kulasingam discussed the formation of the asbestos subcommittee which will develop standards for asbestos measurement for inclusion in Chapter 5, including air, water, and waste, incorporating ISO 17025 concepts. The subcommittee will work cooperatively with the American Industrial Hygiene Association (AIHA) and the National Institute of Standards and Technology (NIST) to complement their existing efforts. Dr. Kulasingam and Mr. Beard will co-chair the subcommittee. The Quality Systems committee has requested guidance from the Board of Directors on this effort.

INTEGRATION OF ISO/IEC 17025 INTO NELAC CHAPTER 5

Dr. Fred Siegelman led this discussion, noting that the current revision of the chapter is consistent with ISO Guide 25, and that gaps between the current chapter and ISO 17025 are being reviewed by the

committee. The copyright restriction is an issue: the current copyright fee is $25,000 per year and ISO may not allow use of the standard on an open website, even with payment of the fee. The NELAC Board of Directors is working on this issue, and incorporation by reference will likely be required. The committee plans to remove all Guide 25 language, including derivative language, from the chapter. Uncertainty will be addressed in these changes, as will some of the PBMS issues. Mr. Siders identified this issue as the committee's first priority; the chapter probably will not be ready for vote by NELAC 7.

PROPOSED CHANGES TO CHAPTER 5

Section 5.9.4.2.1. Initial Instrument Calibration

This section has new language on initial instrument calibration and independence of standards. It was noted that materials are not always independently prepared, even if the paperwork indicates that they are, and tracking the source of standards from the vendor may be difficult. For some analyses (such as pesticides), one source of calibration standard may not be available, much less two; different lot numbers may be the best approach in this situation. It was suggested that a hierarchy of approaches may be appropriate.

Section 5.10.2.1. Demonstration of Capability

There were several comments on this proposed editorial change. Only one demonstration of capability was seen as inadequate by some, since the initial demonstration of capability is no longer specified. Demonstration for instruments that have been inoperative will be revisited. The adequacy of method detection limit studies was questioned, since they may not be performed at the proper concentration.

Section 5.13 Laboratory Report Format and Contents

The proposed new language on confidentiality was seen as too nebulous by one participant.

Section D.2.1 Positive and Negative Controls

There was an objection to the proposed change because degradation of the method can occur undetected if both long-term and short-term control charts are not done. An EPA participant indicated that this is approach from the U.S. Environmental Protection Agency (EPA) toxicity testing method and twenty data points may span 20 months for toxicity testing. It was also noted that using more data can minimize the impact of a few problem points on the overall evaluation.

Section D.2.8 Constant and Consistent Test Conditions

There were no comments on the two changes proposed, one of which had been discussed previously but omitted in the last revision and a clarification.

Section D.5 Air Testing

No comments were made on changes proposed to this section.

PROPOSED CHANGES TO APPENDIX D.3, MICROBIOLOGY TESTING

Ms. Marty Casstevens reviewed the history of this appendix, still a work in progress, and introduced the members of the subcommittee. There were no comments on the proposed introduction. It was noted that in some places "media" will change to "medium" and "accurate" to "acceptable."; will add "and does not demonstrate the typical positive reactions."

Section D.3.1 Sterility, Positive and Negative Controls

The appropriateness of the title of this section was discussed; the subcommittee believes that the included material properly belongs in this section, and not in D3.7. It was also pointed out that some of the topics for microbiology do not fit neatly into the outline. The importance of using the language that the laboratories typically use was voiced; it was suggested that the term "sterility check" be defined. The various types of sterility checks and controls used in microbiology laboratories were reviewed, including the 30 minute limit for performing the sterility checks. Possible elimination of some of the language on positive controls to aid smaller laboratories was questioned and it was observed that some small laboratories are able to do this.

Filters and Dishwashing
Add "filtration equipment and filters." Under 2, strike "in addition to the above media checks" and add "also". Add a number 5 that addresses sterility of water and a number 6 that addresses sterility of new lots of filters (filters may have inhibitory inks). A recent article presented data on membrane filters from different manufacturers and found problems for all. Also, the effects of the dishwashing procedure must be documented; for example, the detergent may effect results.

Section D.3.2 Test Variability/Reproducibility

One participant noted that a laboratory may not be able to analyze duplicate samples, since they may not have control over the number of duplicates collected.

Section D.3.3 Method Evaluation

Demonstration of proficiency by comparison with a second method was discussed extensively. The subcommittee recommends comparison of different methods, since some laboratories avoid methods with higher positive rates. However, use of two methods is being reconsidered by the subcommittee, particularly when one approved method is being used, or in the special instance of start-up laboratories, without existing approved methods. Technical difficulties voiced included: the extent of the necessary comparisons; problems with interferences, since different methods may identify different organisms and are not strictly comparable; necessity for the appropriate initial demonstration of capability. Organizational difficulties mentioned include: applicability to small laboratories; lack of microbiologist staff in drinking water laboratories and initial certification of a laboratory.

The appropriateness of participation in a proficiency test (PT) program in this section was questioned, as was the relationship of Appendix C to the overall system.

Section D.3.4 Test Performance

The issue of what is to be identified was raised. The meaning of "appropriate" was questioned and it was suggested that the word could be deleted. Clarification of "verified" was requested, both in meaning and in the number of hits. A subcommittee member clarified that reference to the methods is sometimes, but not always, adequate.

Section D.3.5 Data Reduction

There were no comments on the proposed changes in this section.

Section D.3.6 Quality of Standards, Reagents and Media

When commercial media does not meet the requirements, a laboratory may need to prepare their own media. Preference for commercial media was questioned and it was noted that preparations can be complex and that there can be variations in the materials used. It was noted that this concept is derived from EPA drinking water methods.

Section D.3.7 Selectivity

In response to a suggestion that this language belongs elsewhere, the subcommittee stated that it believes it is best to retain it.

Section D.3.8 Constant and Consistent Test Conditions

It was suggested that more information on laboratory equipment should be included in some sections. Clarification on the use of data from equipment checks was also requested. A subcommittee member reviewed the role of corrective actions. It was suggested that the differences between chemistry and microbiology may need emphasis in this section.

Temperature Measuring Devices
The performance of thermometers (mercury in glass and others) was discussed and that it tends to vary little with time. It was noted that equipment checks should be appropriate to the specific equipment.

Autoclaves
The acceptance criteria for autoclave testing was raised, as this issue occurs during on-site assessments. It was stated that pressure cookers can still be used for waste decontamination. The last sentence under Autoclaves, iii, will be struck. Autoclaves can be used to melt waste but it is difficult to define specifications for autoclaving wastes, since some loads may require longer decontamination times. References to waste may not be necessary, and it may be outside the scope of the Standard.

Assessor training should include autoclave demonstration testing. Strike "method specific requirements." The tape should be used each time the autoclave is used.

The difference between biological indicators and spore strips was discussed. It was pointed out that Standard Methods includes standard indicators; the bromomethyl blue test and its frequency was discussed and this language will be clarified.

Pressure should be monitored and recorded.

Glassware
Glassware ("labware" may be a better term) should be borosilicate and free of cracks and the specified checks should be performed on labware used repeatedly. Problems that are observed with disposable labware were also discussed and it was noted that plasticizers can create problems.

It was suggested that a washing procedure for non-disposable labware should be specified. Tests for growth promoters/inhibitors was noted as important since some dish detergents promote growth.

The frequency of labware checks was discussed, especially for items that are not used often. It was noted that annual testing can be subcontracted; however records of testing must be maintained.

NEXT STEPS

Mr. Siders will be getting advice from the Board of Directors on
- the asbestos subcommittee,
- the number of compounds for spiking in matrix spikes, and
- method blank criteria.

Other major issues are:
- Integration of ISO language,
- ELAB comments,
- Microbiology changes,
- PBMS issue (including creation of a PBMS subcommittee).
- The on-site checklist may need to be revisited.

All comments received before January 19, 2001, will be addressed.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE MEETING
NOVEMBER 1, 2000

Item No.	Action	Date to be Completed
1.	Form PBMS subcommittee	November
2.	Obtain direction and advice from the Board of Directors on asbestos testing	Next Board meeting

Attachment B

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QUALITY SYSTEMS COMMITTEE MEETING
NOVEMBER 1, 2000

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